

**IN THE UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
EASTERN DIVISION**

UNITED STATES OF AMERICA, <i>ex rel.</i>)	
KEVIN P. MCDONOUGH,)	
)	CIVIL ACTION NO. 2:08-CV-0114
Plaintiff-Relator,)	
)	Judge Marbley
v.)	
)	
SYMPHONY DIAGNOSTIC SERVICES,)	Magistrate Judge Abel
INC. and SYMPHONY DIAGNOSTIC)	
SERVICES NO.1, INC., d/b/a MOBILEX,)	ORAL ARGUMENT REQUESTED
U.S.A,)	FILED UNDER SEAL
)	
Defendants.		

DEFENDANTS' MEMORANDUM OF LAW
IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT

Symphony Diagnostic Services, Inc., and Symphony Diagnostic Services No. 1, Inc., d/b/a Mobilex U.S.A. (collectively "Mobilex") files this Memorandum of Law in Support of their Motion for Summary Judgment, stating as follows:

I. INTRODUCTION

Mobilex is the largest provider of mobile x-ray and diagnostic services in America. Its customers are skilled nursing facilities ("SNFs," usually pronounced "sniffs"), long-term acute care hospitals, prisons, and other institutions that provide health care. Mobilex serves patients and residents at these facilities so that they do not have to travel to a hospital or other location for the x-ray, ultrasound, EKG, or other service. The residents at SNFs who receive services from Mobilex are covered under Medicare, Medicaid, or private health care coverage, each of which pays under a different payment regime.

When Mobilex serves a Medicare Part A patient (Part A pays for hospitalization and post-acute care), Mobilex bills the SNF directly. The SNF then pays Mobilex directly at

negotiated contract rates pursuant to the reimbursement system established by the government. When Mobilex serves a Medicare Part B patient (Part B pays for medically necessary services not covered in a Part A stay – labs, physicians, diagnostic services, etc.), Mobilex bills the federal Government, which then pays Mobilex directly at rates set unilaterally by the Government and published in the Medicare Fee Schedules (“MFS”) for each state. The rates in the MFS are frequently higher than the rates which the SNFs negotiate with Mobilex or its competitors under the Medicare Part A payment regime.

Relator Kevin McDonough sued Mobilex in the U.S. District Court for the Southern District of Ohio under the *qui tam* provisions of the federal civil False Claims Act (“FCA”), 31 U.S.C. § 3729, *et. seq.* Relator is a former Mobilex competitor in parts of Florida and Georgia. He was also worked briefly for Mobilex, until the company terminated him for unprofessional conduct unrelated to this litigation. At this point, Relator’s action is based solely on his allegation that Mobilex charged rates to SNFs that were below Mobilex’s costs and fair market value (“FMV”). Relator contends that Mobilex engaged in an economic “swap” by providing the Medicare Part A services as a loss leader, in return for access to patients covered under Medicare Part B. In other words, he alleges that Mobilex cross-subsidized losses under Medicare Part A with payments by the Government under Medicare Part B, which is illegal under the federal Anti-Kickback Statute (“AKS”). The government declined to intervene in Relator’s *qui tam* complaint against Mobilex, and Relator has made the decision to proceed against the company without the Government.

This case involves an unusual question: Can a Relator survive summary judgment based upon his putative expert’s legal conclusions and related FMV analysis (which is not grounded in the AKS) where the Relator lacks any specific evidence, document, report, email, or analysis

suggesting that the defendant knowingly and willfully priced its Part A services below some measure of its costs? That is, can a Relator survive judgment without any individualized evidence related to the negotiation of rates for a specific SNF, when the heart of Relator's claim is the alleged violation of the AKS, which is federal criminal statute? The answer is straightforward, especially given Relator's putative expert's concession that her statements of the "law" (with which Mobilex disagrees) are "overstated." There is no dispute regarding any material fact and Mobilex is entitled to summary judgment.

As set forth more fully below, Relator cannot show under any interpretation of the AKS that Mobilex has knowingly and willfully provided remuneration to its SNF customers in the form of below-cost or below-FMV rates for Part A services in return for the referral of business paid for by Medicare Part B. Nor can Relator demonstrate that the calculations of "costs" and "fair market value" that he and his putative expert have tendered have ever been accepted by any court ruling on an AKS violation. Nor can Relator show that, even if his theories were correct, that there is any evidence (*e.g.*, an email, memoranda, or witness testimony) that raises a triable fact issue concerning what is undisputed: Mobilex always intended to negotiate contracts with SNFs that were profitable on the Part A side, the Part B side, and on the whole.

Mobilex's motion for summary judgment should be granted.

II. STATEMENT OF UNDISPUTED FACTS

A. Relator is a former Mobilex competitor who obtained work with the company and was then terminated for unprofessional conduct after only 11 months

Relator is the former owner and operator of a mobile x-ray business that competed against Mobilex's predecessors in Florida and Georgia, allegedly from 1983 through 1999, and 1994 through 1999, respectively. Dep. of Kevin McDonough ("R. Dep.") at 9-11; 13-14 (all excerpts attached as Exh. 1). He believes that Mobilex's corporate predecessor put him out of

business by offering lower prices to SNFs, allegedly in violation of the Anti-Kickback Statute (“AKS”). *See* R. Dep. at 33-36. Since the late 1990s, Relator has criticized Mobilex to other mobile x-ray companies,¹ while also emerging as a serial *qui tam* relator against mobile x-ray companies and SNFs in the courts.

Those *qui tam* actions have included *U.S. ex rel. McDonough v. Delta Health Group, Inc.*, in which Relator alleged under seal that several nursing homes engaged with Mobilex in a fraudulent “cost-masking” scheme. No. 6:02cv01271 (M.D. Fla., filed Oct. 25, 2002). Like this case, the Government declined to intervene. *Id.* at ECF No.2. The district court threatened to dismiss for want of prosecution in May 2005, and Relator’s counsel withdrew in June 2005.² The case was dismissed for want of prosecution in January 2006. *Id.* at ECF No. 6.

With his business having collapsed and his FCA case dying on the vine, Relator pursued and obtained work with Mobilex in October 2005. *Id.* at ECF Nos. 3, 4, 7, 9; Dec. of William Glynn (“Glynn Dec.”) (attached hereto as Exh. 3). Relator failed to tell Mobilex that at the same time he was seeking work at the company, he was also suing Mobilex’s customers in *Delta Health* for allegedly defrauding the Government and, in the process, alleging that Mobilex was

¹ For example, Relator held a leadership position within the National Association of Portable X-Ray Providers (“NAPXP”), which is the trade association for the independent mobile x-ray industry (Mobilex is not a member). R. Dep. at 17. At one of the NAPXP’s annual meetings in the late 1990s, McDonough handed out coffee mugs that stated: “F#@K Mobilx.” *Id.* at 160-161, Exh. 4 to deposition transcript; Declaration of Brian Stimson (“Stimson Dec”) (attached hereto as Exh. 1(a)).

² In total, Relator has filed five *qui tam* actions. In addition to *Delta Health*, which was dismissed for want of prosecution on January 27, 2006, the most recent include: *U.S. ex rel. McDonough v. Koplowitz*, No. 0:10cv61570-WPD (S.D.Fla., filed Aug. 26, 2010), in which Relator obtained a default judgment against a seemingly insolvent defendant as well as a walk-away settlement with the remaining defendants; and *U.S. ex rel. McDonough v. Colon*, No. 8:10cv01889-EAJ (M.D.Fla., filed Aug. 25, 2010), in which Relator settled with a client of his mobile x-ray consulting business for the costs of defense at trial (\$50,000). While *Delta Health* was pending, Relator wrote a book foreword glorifying his whistleblowing activities. Kevin McDonough, *Foreword* to John W. Schilling, *Undercover: How I Went from Company Man to FBI Spy and Exposed the Worst Healthcare Fraud in U.S. History*, at vii-ix (Am. Mgmt. Ass’n 2008). He also became a partner in a consulting company whose mission was to help putative whistleblowers develop successful FCA lawsuits against health care companies. *The Good, the Bad & the Ugly: An Historical Perspective of Lessons Learned in our Health Care Fraud Qui Tam Cases*, Kevin McDonough (McDonough’s excerpt of PowerPoint for “EthicsSolutions LLC” attached with book foreword as Exh. 2).

involved in the fraud. Relator then used his position with Mobilex to try to build a case against the company by taking documents from the trash that Mobilex asked him to discard. R. Dep. at 140:1-24.

Relator's role at Mobilex was focused almost exclusively on integrating Regional Diagnostics, a newly-acquired mobile x-ray company in Ohio. R. Dep. at 72-73; Glynn Dec. at ¶ 16. With the exception of a brief stint in Florida, Relator did not work in any other Mobilex corporate region. *See* R. Dep. at 155:21-156:23; Glynn Dec. at ¶ 16. The company terminated him for unprofessional conduct unrelated to this case in September 2006, after only 11 months of work.³ Relator responded to his dismissal by taking and then driving a Mobilex-issued company car to Virginia to meet with one of Mobilex's competitors. R. Dep. at 156:24-160:12. Only after Mobilex engaged law enforcement did he finally return the car. Glynn Dec. at ¶ 18, Attach. 3. On February 7, 2008, approximately one year after returning the car, he filed this action against Mobilex and a number of SNF chains under seal.

B. Mobilex is a national provider of mobile x-ray services that competes vigorously against regional and local mobile x-ray providers and hospitals

Mobilex contracts with SNFs, long-term acute care hospitals, prisons, and other health care facilities to provide mobile x-ray services and other diagnostic services like EKGs and ultrasounds to the patients residing there. By providing these services where the patient resides, Mobilex relieves them from traveling to another location for the service. The diagnostic tests are conducted by a technician and the results are transmitted to a radiologist or other physician for interpretation.

³ R. Dep. at 102:20-21; Glynn Dec. at ¶ 17, Attach. 2. Relator initially pled a claim for retaliation under the False Claims Act. The Court granted Mobilex's motion to dismiss that claim, finding that Relator had not credibly alleged that he complained to his supervisor about the matters set forth in his Amended Complaint before he was terminated for his unprofessional conduct. ECF No. 51 (Feb. 27, 2012).

This case involves patients who reside at SNFs and the method by which Mobilex is reimbursed for those tests. The patients at the SNFs may be covered under Medicare Part A, Medicare Part B, Medicaid, other government insurance (*e.g.*, TRICARE), private health care coverage, or self-insurance. *See* Dep. of William Glynn of June 27, 2013 (“Glynn II”) at 11:8-12:20 (all excerpts attached hereto as Exh. 4). Mobilex (and often the SNF) learns the insurance coverage information only *after* providing the services to the patient. Dep. of William Glynn of Nov. 2, 2012 (“Glynn I”) at 41:2-5, 103:7-23, 145-146 (all excerpts attached hereto as Exh. 5). That is, at the time a service is ordered and a test performed on a patient at a SNF, Mobilex does not know which payor or payment methodology will pay for the examination.

1. The methodologies by which Mobilex is reimbursed are numerous and complex

The mobile x-ray services which Mobilex provides to SNFs are reimbursed under various payment regimes. Generally, [REDACTED] of the SNF patients Mobilex serves are covered through Medicare Part A. [REDACTED] are covered through Medicare Part B, and [REDACTED] are covered through private health care coverage, Medicaid, or self-pay. Glynn II Dep. at 11:8-12:16. We describe each of these below:

Medicare Part A

When Mobilex serves a Medicare Part A patient,⁴ it bills the SNF directly. CMS Pub. 100-04, ch. 13 § 20.2.1 (Rev. 2750, Aug. 2, 2013). The SNF then pays Mobilex at contract rates that are nonexclusive and negotiated by Mobilex in competition with other mobile x-ray providers.⁵ CMS Pub. 100-04, ch. 6 § 10.4 (Rev. 2573, Oct. 26, 2012). In turn, the SNFs

⁴ Medicare Part A pays for hospitalization and post-acute inpatient care. 42 U.S.C. § 1395d.

⁵ Mobilex negotiates for Part A business with SNFs by contract and not by individual x-ray exams or individual patient encounters (which may include multiple exams). Glynn Dec. at ¶ 6. Each contract may encompass one or dozens of SNFs, depending on whether the SNF is run independently or as part of a national chain. Glynn I Dep. at 54:11-55:3; Dep. of Robbin Reichert (“Reichert Dep.”) at 65-66 (all excerpts attached hereto as Exh. 6). In addition

submit their own claims for payment to the Medicare program. CMS Pub. 100-04, ch. 13 § 20.2.1 (Rev. 2750, Aug. 2, 2013). Medicare then pays the SNF a per diem rate for the service provided to the patient at the SNF. Generally, the per diem paid under Medicare Part A is all-inclusive. The per diem is expected to cover all of the SNF's costs including, among other things, room and board, labs and nursing. 42 C.F.R. § 413.1(g).

This Medicare Part A payment regime is known as the "Prospective Payment System" or "PPS," and was implemented for cost reporting periods beginning on or after July 1, 1998. Balanced Budget Act of 1997, Pub. L. No. 105-33, §4432, 111 Stat. 251, 414. PPS was designed to encourage price competition among mobile x-ray companies and other providers serving SNF patients, and thereby lower costs.⁶ Before PPS, the Medicare program reimbursed all mobile x-ray providers through direct payments similar to those which it now makes only for Medicare Part B patients. H.R. Rep. No. 105-149, at 1313-15.

Medicare Part B

When Mobilex serves a Medicare Part B patient,⁷ Mobilex bills the Medicare program or Medicare's Part B carrier directly. CMS Pub. 100-04, ch. 7 §50 (Rev. 1472, March 6, 2008); CMS Pub. 100-04, ch. 13 §§ 10.1, 90 (Rev. 2750, Aug. 2, 2013). Medicare then pays Mobilex directly at rates set unilaterally by the Government and published in the Medicare Fee Schedule

to setting forth Mobilex's rate to serve Part A patients, each contract generally obligates Mobilex to provide services for any patient for whom the SNF requests services, including Part B patients. Glynn Dec. at ¶ 6.

⁶ See H.R. Rep. No. 105-149, at 1317-18 (1997) ("The Committee believes that moving from cost-based reimbursement to prospective payment, which rewards efficiency, will make Medicare a more prudent purchaser of these services"); *see also* 143 Cong. Rec. S6094 (daily ed. June 23, 1997) (statement of Sen. Hatch) ("It is extremely important that we change the existing and limited incentives in the Medicare system so that providers will offer services in the most cost-effective way."); Jennifer O'Sullivan *et al.*, Cong. Research Serv., 97-640 EPW, Medicare: Budget Reconciliation Action in the 105th Congress (1997) ("Cost-based reimbursement has been cited as one of the reasons for significant growth in SNF spending since 1989... Increases in ancillary service reimbursements explain much of this per diem payment growth.")

⁷ Medicare Part B pays for medically necessary services received during an inpatient stay which are not covered by Medicare Part A, such as physician, laboratory, and diagnostic services. 42 U.S.C. §1395k.

(“MFS”) for each state. CMS Pub. 100-04, ch. 13 §§ 10.1, 90 (Rev. 2750, Aug. 2, 2013). It is undisputed that the rates in the MFS are not established in the competitive market but are instead set by the Government. Thomas McCarthy Report (“McCarthy Rpt.”) at 15 (attached hereto as Exh. 7); *cf.* Dep. of Kathy McNamara (“McNamara Dep.”) at 61 (attached hereto as Exh. 8). Accordingly, they may be higher than the Medicare Part A rates which the SNFs negotiate with Mobilex.

Private Health Care Coverage

When Mobilex serves a patient with private health care coverage, such as a group plan or an individual insurance policy, Mobilex’s billing depends on whether it has contracted with the plan administrator or insurer. If Mobilex is contracted, then it typically bills the plan administrator or insurer directly. Glynn Dec. at ¶ 9. If Mobilex is non-contracted, then it tries to obtain the patient’s coverage information plus an assignment of benefits from the patient at the point of service, so that it can bill the plan administrator or insurer directly. *Id.* Otherwise, Mobilex must seek payment from the patient *after* the patient receives payment of his or her benefits under the plan or policy. *Id.*

Self-Pay Patients

Self-paying patients cover their own health care costs completely out of pocket, and are not members of a group plan or health insurance policyholders. Self-pays can be persons with means sufficient to pay for significant health care costs out of pocket. Glynn Dec. at ¶ 10. But more often than not, self-pays are persons who do not qualify for government insurance yet lack the means to purchase private health insurance. *Id.* Mobilex must bill and try to collect payment directly from self-pays, who often lack the means to pay notwithstanding their knowing acceptance of Mobilex’s services. *Id.*

2. The market for diagnostic x-ray services is competitive, characterized by low barriers to entry, low capital costs, and high turnover

Mobilex's competitors can include small mobile x-ray providers (like those formerly run by Relator), or larger, multi-state or multi-city entities designed to serve not only local markets but also regional or national SNF chains. Glynn Dec. at ¶ 14. [REDACTED] of Mobilex's SNF contracts turn over each year. McCarthy Rpt. at ¶ 16; *see also* Dec. of Margaret Sanderson (attached hereto as Exh. 9, Attachs. 1-4) (providing examples of Mobilex win/loss reports). This is because when a SNF is dissatisfied with Mobilex's (or a competitor's) quality or pricing it can turn to another willing bidder to provide mobile x-ray services. McCarthy Rpt. at ¶ 16. Moreover, Mobilex's contracts are typically terminable [REDACTED] [REDACTED]. *Id.* at 14. Price and quality are often triggers that motivate SNFs to consider changing mobile x-ray service providers. A SNF, for example, may be concerned about response time, turn-around time, availability (*e.g.*, nights and weekends coverage, stat service, scheduled service), accuracy, and current technology (*e.g.*, digital radiology, online access for reporting).⁸ The significant turnover in Mobilex's SNF contracts means that Mobilex's pricing reflects vigorous, persistent competition, as intended by the PPS regulations. *Id.* at ¶ 15.

Such competition exists in the market due to the low barriers to entry. Many mobile x-ray businesses are founded by individuals. *Id.* at ¶¶ 18, 22. Indeed, Relator claims to have started a mobile x-ray business "out of the trunk of [his] car." *Id.* at ¶ 21, n. 32 (citing R. Dep. at 30-31, 254-56). Expansion from that point can be easy due to low initial investment, the

⁸ *Id.* at n.18 (citing Dep. of David Williams ("Williams Dep.") at 43-44, 101-102 (all excerpts attached hereto as Exh. 10); Glynn II Dep. at 70-73; Dep. of Jeff Hooper ("Hooper Dep.") at 28-29 (all excerpts attached hereto as Exh. 11)).

feasibility of incremental expansion, and short termination clauses.⁹ Small providers can grow into statewide or regional competitors in just a few years. McCarthy Rpt. at ¶¶ 17, 18 at n. 21-28. Small providers are often aggressive competitors on price, sometimes to levels that Mobilex cannot match. *Id.* at ¶ 18 at n. 30 (citing Glynn I Dep. at 136-37).

The market for mobile x-ray services is competitive,¹⁰ and Mobilex's contract prices reflect competitive market prices. *Id.* at ¶ 22.

3. Mobilex may offer alternate pricing structures when competing for Part A business

Mobilex offers three different pricing structures to SNFs for services furnished to Part A patients. [REDACTED]

[REDACTED] Glynn I Dep. at 44:23-45:4. MFS-based rates are a percentage of the state MFS rate per exam or patient encounter. *See* Glynn I Dep. at 77:17-78:3. Flat rates are a negotiated fee per exam or patient encounter. Glynn I Dep. at 47-48, 86. Per diems are priced as a per capita fee per patient day ("PPD") based on the number of Part A patients at the facility each day. Glynn I Dep. at 49.

Importantly, per diems are risk-bearing contracts. That is, they are flat rates paid per patient, per day, regardless of how many x-rays Mobilex performs on any individual patient on a specific day. Reichert Dep. at 32-38. Under this structure, the effective payment per exam can vary dramatically depending on the number of exams performed. In some months, Mobilex may perform relatively few exams while in other months—for example, where there is a busy flu season—it may perform substantially more. Williams Dep. at 55:15-17; Hooper Dep. at 24:17-

⁹ *Id.* at ¶ 21, n.34 (citing R. Dep. at 179-80), n.35-36, n.37 (citing Glynn I Dep. at 66-68), n. 38 (citing SDS013898-3906 at SDS013899; SDS009061-9069 at SDS009061; SDS009088-9095 at SDS009089; SDS009367-9384 at SDS009369; SDS112030-2041 at SDS112032; SDS140697-0708 at SDS140697; SDS096422-6443 at SDS096422; SDS047182-7191 at SDS047184); Dec. of Robbin Reichert ("Reichert Dec.") at ¶ 15 (attached hereto as Exh. 12).

¹⁰ Also, Mobilex competes with facility-based providers of x-ray services. Hospitals, for example, are seeking to provide more x-rays in post-acute settings. This is because Medicare providers, including many newly-formed Accountable Care Organizations, are now penalized for unnecessary hospital readmissions. *Id.* at ¶ 19.

18. Unexpectedly high service levels can produce losses. Likewise, unexpectedly low service levels can produce gains. Glynn I Dep. at 48-49. With per diem contracts, Mobilex and the SNF seek to negotiate a rate in advance based upon an estimated number of Part A patients. See Glynn II Dep. at 48:25-50:5. This is an inherently variable exercise because neither party knows with certainty in advance how many patients will require services.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

4. Mobilex always expects that the prices negotiated with SNFs for Part A business will cover the anticipated cost of providing the service

Every single current and former Mobilex employee involved in pricing SNF contracts testified unequivocally that when Mobilex contracts with a SNF, it always expects to cover its anticipated costs of providing the service. Glynn II Dep. at 98:8-15; Dep. of Patricia Pawling (“Pawling Dep.”) at 45:8-10 (all excerpts attached hereto as Exh. 13); Reichert Dep. at 18-19; 134-136; Williams Dep. at 112; Hooper Dep. at 16-17. In other words, Mobilex expects—at a minimum—to cover its anticipated incremental cost (referred to interchangeably as average variable cost) of providing the service. Mobilex also expects to make a profit on every contract which it enters into with a SNF. Glynn I Dep. at 145:20-23; Glynn II Dep. at 33:14-21; 76:14-17; Reichert Dep. at 134-136; Hooper Dep. at 16-17. Not surprisingly, Mobilex has made a

corporate-wide profit every year from 2004 up through the present, including during the recession years. Dec. of Brian Cuomo at ¶¶ 10-18 (“Cuomo Dec.”) (attached hereto as Exh. 14).

Mobilex employees have testified that they intend for the Part A rate to be profitable on its own, meaning that it covers, at the very least, the company’s anticipated incremental costs of providing services to Part A patients separate from Part B patients. Williams Dep. at 71 (explaining that when setting rates with SNFs “the idea was to have a rate that was profitable on a stand-alone basis.”). Their focus is not on actual SNF-specific costs because Mobilex’s actual costs can vary greatly from day to day, and SNF to SNF, based upon myriad factors relating to service delivery: the SNF’s patient volume, how the service is structured for the SNF, the technology used for the SNF, the SNF’s proximity to the Mobilex operator’s other customers’ facilities, the number of patients served by the Mobilex operators at other customers’ facilities, the costs of local inputs, and seasonal demands (*e.g.*, summer versus flu season) can all impact the calculus.¹¹ The dynamic variability in day-to-day service delivery presents insurmountable cost allocation problems, which make cost accounting at the SNF or more granular exam or encounter levels impracticable. McCarthy Rpt. at ¶ 30, n. 54 (citing Pawling Dep. at 32). This is especially true because when Mobilex negotiates a contract with the SNF, it may never have served the SNF before and may have no experience with the service variability unique to the SNF.¹²

Mobilex’s situation is not uncommon. [REDACTED]

[REDACTED]

¹¹ McCarthy Rpt. at ¶ 39, n. 75 (citing Reichert Dep. at 87-88), n. 76 (citing Reichert Dep. at 23-26), n. 77 (citing Hooper Dep. at 111-112, Glynn II Dep. at 70-71), n. 78 (citing Hooper Dep. at 105-106, Glynn II Dep. at 72-73, 91), n. 79 (citing Williams Dep. at 17, 50, Hooper Dep. at 39-40), n. 80 (citing Hooper Dep. at 39-40, 166), ¶ 40, n. 81 (citing Hooper Dep. at 24); Pawling Dep. at 33:16-20.

¹² Williams Dep. at 14-16.

[REDACTED]

[REDACTED]

[REDACTED] Indeed, there is no evidence in this case that any mobile x-ray company has ever reliably ascertained its actual costs to serve at the facility or exam level.¹³

Consequently, Mobilex uses overall profitability, average measures of revenue and cost on a more consolidated basis, and other business tools as guides when negotiating contracts with SNFs. Glynn I Dep. at 144-145; Reichert Dep. at 82-83. Mobilex, for example, divides its nationwide business into multi-state regions, and then divides the states in those regions into geographic cost centers. Glynn I Dep. at 31:6-32:4, 61:1-6. The regions and their constituent states and cost centers are managed by Regional Vice Presidents (“RVPs”), who oversee the sales personnel and sign the SNF contracts. Glynn I Dep. at 57:13-22. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] provided to the RVPs are neither audited financial statements nor mandated by federal or state law, nor are they required by Generally Accepted Accounting Principles (“GAAP”). Cuomo Dec. at ¶ 8. Rather, the RVPs use the P&Ls, together with their knowledge of service variability in their regions, to make forward-looking contracting decisions. Reichert Dep. at 81-83; Williams

¹³ Relator posits that the analysis is practicable, but neither Relator nor any other witness has posited a method for conducting a reliable analysis, much less identified a mobile x-ray company that has performed a reliable analysis. Indeed, Kathy McNamara, who Relator has produced as his putative expert on cost and FMV, conceded that it was impossible for her to identify Mobilex’s actual costs to serve each of the 3,000 facilities for which she received information from Relator’s counsel. McNamara Dep. at 140:7-16.

Dep. at 56, 98:20-100:6. Although the P&Ls are helpful business tools in the aggregate, RVPs cannot make informed contracting decisions for individual SNFs based solely on the P&Ls, because the P&Ls do not reflect service variability at the SNF level.¹⁴ Glynn Dec. at ¶ 13.

5. Mobilex conducts annual rate reviews of its SNF contracts in order to identify Part A rates warranting further assessment for compliance with the AKS

Notwithstanding the impracticability of determining the actual costs of providing service at the individual SNF level, Mobilex conducts an annual review of its mobile x-ray contracts in which the RVPs are asked to review pricing for SNFs in their region, and further assess those with [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] If the RVP finds that the rate presents compliance concerns then the RVP will try to increase the rate, restructure the service to reduce costs, or, as a last resort, discontinue the service. Williams Dep. at 104-107; Glynn I Dep. at 63-65; Glynn II Dep. at 67, 83-84; Pawling Dep. at 53-54.

Mobilex implemented this current, more formalized version of its rate review program in approximately 2007,¹⁶ [REDACTED]

¹⁴ Mobilex's forward-looking contracting analysis is further complicated by the different revenue levels produced by the three alternative pricing structures. McCarthy Rpt. at ¶¶ 30-31; Reichert Dep. at 35:22-38:13.

¹⁵ Mobilex recognizes that, as a health care provider, it is subject to the AKS and it has taken steps to ensure compliance. Indeed, its compliance program was reviewed and accepted by the HHS-OIG during the term of a Corporate Integrity Agreement ("CIA") to which Mobilex was bound by one of its predecessor companies. *See generally*, Glynn I Dep. at 14-21.

¹⁶ It is undisputed that Mobilex has conducted rate reviews since at least 2003. Dec. of Patricia Pawling ("Pawling Dec.") (attached hereto as Exh. 17). In approximately 2007, Mobilex implemented its current, more formalized rate

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

It is undisputed that Mobilex's rate review program is effective. Even Kathy McNamara, Relator's putative "valuation" expert (who Mobilex will be moving to exclude), has admitted this. She testified at her deposition that, year-over-year, the rate review program has systematically increased Mobilex's rates with those SNFs appearing on the [REDACTED]

[REDACTED]

[O]ver the course of the three years analyzed ... [REDACTED]

[REDACTED]

[REDACTED]. So they did raise the rates for some of those facilities.

McNamara Dep. at 188:25-189:8.

An examination of the rates for the 11 SNFs named in Paragraph 78 of Relator's Amended Complaint¹⁷ as well as the additional 337 SNFs that Relator named as "focus" facilities¹⁸ demonstrates the effectiveness of the rate review process. The vast majority of these SNFs have exceeded [REDACTED]

review program [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

¹⁷ Relator listed 11 SNFs in Paragraph 78 of his Amended Complaint, one of which is identified as "Manor Care Westerville." Mobilex's records indicate that this could be one of two facilities; therefore Mobilex has assumed that one of those two facilities is part of Relator's original 11 SNFs. It is not uncommon for Mobilex to service SNFs with similar names, because Mobilex services over 6,000 facilities nationwide. *See* McCarthy Rpt. 2.

¹⁸ ECF No. 86 (June 12, 2013). Mobilex produced substantial information on the 11 SNFs in Paragraph 78 of Relator's Amended Complaint, including Mobilex's entire contract file and history for each SNF. Relator then moved to compel contract files, emails, and internal memoranda and the like for eight more individual SNFs, plus three SNF chains. *Id.* Mobilex's contracts with those three SNF chains encompass 329 SNFs. Reichert Dec. at ¶ 15. In total, the 348 SNFs targeted by Relator operate in 25 states spread across the country: AL, AR, CT, FL, GA, IN, KS, KY, MA, MD, MI, MN, MO, MS, NC, NE, NH, NJ, OH, OK, PA, TN, TX, VA, and WI.

██████████ but also exceeded Mobilex’s corporate-wide incremental cost per encounter. Of those 348 SNFs, ██████████ David Yarin Report (“Yarin Rpt.”) at Exh. D (attached hereto as Exh. 18). Twenty-six averaged between ██████████ per encounter, 45 averaged between ██████████ per encounter, and ██████████ per encounter or higher during their respective contract periods. Dep. of David Yarin (“Yarin Dep.”) at 107-108 (attached hereto as Exh. 19). Indeed, three of the SNFs that Relator deemed as “focus” facilities received ultrasound but no x-ray services from Mobilex. *Id.* at 109.

6. The pricing that Mobilex offers to prisons, which do not have any Part B business, is consistent with the pricing which Mobilex offers to SNFs for Part A business

One way to examine FMV is to examine the prices negotiated by Mobilex where there is no prospect of an alleged “swap” because there is only a single payment methodology. Mobilex serves many prisons across the country that meet this criteria. Reichert Dec.at ¶ 4. The prisons pay negotiated rates to Mobilex for the services which the company furnishes to inmates. *Id.*at ¶ 6. Mobilex does not bill Medicare Part B for any of those services. *Id.* It is undisputed that Mobilex has entered into 47 prison contracts during the relevant time period that provided for a per exam rate. *Id.* at Attach. 1. As with SNF contracts, Mobilex negotiates the rate with each prison, but unlike SNFs there is no possibility of Part B revenue. [REDACTED]

Id. at ¶¶ 10-13.

¹⁹ For the purposes of this comparison, the distribution of the Part A contract rates for the SNF are “per exam” and not “per encounter” as discussed in Section II.B.5.

Rate Per Exam	# Prison Contracts	% Prison of 47 Contracts	# SNF Contracts	% SNF of 348 Contracts ²⁰
Less than \$65.00	█	█	█	█
\$65.00 - \$74.99	█	█	█	█
\$75.00 - \$84.99	█	█	█	█
Greater than \$85.00	█	█	█	█

7. The alleged “swapping scheme” is implausible given the year-over-year variations in Mobilex’s Part A charges versus Mobilex’s Part B payments

Relator’s alleged swapping scheme is implausible because Mobilex’s Part A charges to SNFs²¹ indisputably varied and, in many years, exceeded the Medicare Part B payments received by the company. Take, for example, the 11 SNFs named in the Amended Complaint, plus the additional 337 SNFs on which Relator moved to compel discovery and was denied. ECF No. 86 (June 12, 2013). It is undisputed that from 2004 through 2012, Mobilex’s total Part A charges and Part B payments were:

Year	Part A Charges	Part B Payments	Difference (A minus B)	Part A as % of Total
2004	█	█	█	█
2005	█	█	█	█
2006	█	█	█	█

²⁰ The total of numbers of SNFs included in the chart is 345 and not 348 because only ultrasound services were performed at three of the 348 SNFs. See Section II.B.(4).

²¹ Part A charges are the most reliable proxy for Part A payments received from SNFs because Mobilex collected more than █ of its total charges. Yarin Rpt. at 13.

2007	██████	██████	-██████	██████
2008	██████	██████	-██████	██████
2009	██████	██████	██████	██████
2010	██████	██████	██████	██████
2011	██████	██████	██████	██████
2012	██████	██████	██████	██████

Yarin Rept. at Exh. C. It is undisputed that across this entire time period, the total Part A charges on average exceeded █████ or greater of Mobilex's combined Part A charges and Part B payments. *Id.* at 12.

If a "swapping scheme" was occurring as Relator posits, then the Part B payments would have had to exceed the Part A charges. This is because Mobilex would have had to receive Part B payments in excess of the Part A payments in order to offset the below-cost or below-FMV rates given to SNFs under Medicare Part A. That scenario has not occurred:

██

██

██

██████e. This is simply not the stuff of a "swapping scheme."

C. Relator's case has narrowed dramatically since 2008, to the point where he has now conceded that there was no swapping at 8 of the SNFs in his Amended Complaint and is targeting fewer than 348 SNFs

Relator sued on February 7, 2008, in the name of the Government and thirteen states. ECF No. 2. He took a conspiratorial, scorched-earth approach by naming Mobilex, Mobilex's investors, eight of Mobilex's SNF chain customers, and two of Mobilex's affiliated radiologists

as defendants. *Id.* at ¶¶ 16-54. The Government investigated and declined to intervene on September 16, 2010. ECF No. 19. The States declined to intervene on February 3, 2011. ECF No. 23. Relator exercised his statutory right to proceed independently of the Government, serving Mobilex in April 2011. ECF No. 24 (Apr. 7, 2011). The next month Relator amended his Complaint to proceed against Mobilex as the sole defendant. ECF No. 31 (May 26, 2011). Keeping to his conspiratorial approach, Relator still alleges a nationwide swapping scheme, yet identifies only 11 SNF contracts from Ohio and Indiana with any specificity. *Id.* ¶ 78.

Since receiving the Amended Complaint in May 2011, Mobilex has responded to 67 document requests by producing more than 28,000 documents, answered 16 interrogatories, and produced 8 fact and 4 expert witnesses for deposition. After obtaining that discovery, Relator still has no Mobilex witness testimony, emails, internal memoranda or the like showing that specific Mobilex personnel knowingly or willfully charged rates to the 11 original SNFs (or any other SNFs for that matter) that violated the law. Indeed, Kathy McNamara, who Relator produced as his putative damages expert (and who Mobilex will be moving to exclude), does not include 6 of the 11 SNFs from the Amended Complaint in her damages model. Of the 5 SNFs that are included, she does not attribute damages for 2 SNFs, because even she was forced to concede that Mobilex's rates with those 2 SNFs were not below FMV or Mobilex's costs. Kathy McNamara Report ("McNamara Rpt.") at Appx. C (attached hereto as Exh. 20).

Recognizing that Relator had no case regarding pricing to the 11 SNFs named in the Complaint, Relator moved to compel Mobilex to produce contract files and documents for an additional 337 SNFs (consisting of 8 independent SNFs, plus 329 SNFs affiliated with three national SNF chains).²² ECF No. 86 (June 12, 2013). The Court denied the motion because

²² Before Relator moved to compel, Mobilex served an Interrogatory asking Relator to identify the SNF contract rates that he contends are below costs. Relator's Objections and Responses to Mobilex's First Interrogatories, at No.

Relator could not show—using the evidence adduced regarding the original 11 SNFs²³—that the additional discovery relating to the 337 SNFs would yield an evidentiary benefit exceeding the burden on Mobilex. *Id.* In other words, the Court refused the additional discovery relating to the 337 SNFs, because after more than five years Relator could not show that additional discovery was warranted or that additional documents would support his claims. *See id.* Plainly, the Court has every reason at this juncture to grant summary judgment in Mobilex’s favor, especially now that Relator’s putative damages expert has conceded that no swapping occurred at 8 of the original 11 SNFs.

III. ARGUMENT AND CITATION OF AUTHORITIES

A. Standard of Review for Summary Judgment in the Sixth Circuit

When determining if summary judgment is appropriate, the Court asks “whether the evidence presents a sufficient disagreement to require submission to a jury or whether it is so one-sided that one party must prevail as a matter of law.” *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 251-52 (1986). “The moving party has the initial burden of showing the absence of a genuine issue of material fact as to an essential element of the non-moving party’s case.” *Martingale LLC v. City of Louisville*, 361 F.3d 297, 301 (6th Cir. 2004) (cits. omitted). To that end, the court must view the evidence “in the light most favorable to the non-moving party.” *Doren v. Battle Creek Health Sys.*, 187 F.3d 595, 597 (6th Cir. 1999) (cits. omitted).

8 (attached hereto as Exh. 21). Relator’s response—which still stands—has been to generically refer Mobilex to documents that Relator produced to Mobilex in discovery, without identifying which SNF contracts referenced in those documents were allegedly below costs. *Id.* To date, the only SNF contracts which Relator has alleged with specific rate information are the original 11 from his Amended Complaint.

²³ When Relator moved to compel, he had already obtained substantial discovery regarding the 337 SNFs, as Mobilex’s document productions contain documents relating to Mobilex’s SNF business generally. The productions also included *all* of Mobilex’s payment and charge data for *all facilities*. Relator objected to the size of this data, and Mobilex has since produced to Relator a subset of the payment and charge data tailored specifically to the 348 total SNFs targeted by Relator. Relator, by his counsel’s admission, has not used this tailored data.

“Once the moving party satisfies its burden, the burden shifts to the non-moving party to set forth specific facts showing a triable issue.” *Martingale*, 361 F.3d at 301. “The mere existence of a scintilla of evidence in support of the plaintiff’s position will be insufficient; there must be evidence on which . . . reasonable jurors could find by a preponderance of the evidence that the plaintiff is entitled to a verdict.” *Anderson*, 477 U.S. at 252. “Conclusory statements unadorned with supporting facts are insufficient to establish a factual dispute that will defeat summary judgment.” *Alexander v. CareSource*, 576 F.3d 551, 560 (6th Cir. 2009) (cits. omitted). Specifically, affidavits that contain no “specific facts” “are merely conclusory, restating the requirements of the law, and therefore cannot create a genuine issue of material fact sufficient to defeat summary judgment.” *Doren*, 187 F.3d at 598-99.

The Sixth Circuit “requires the nonmoving party to ‘put up or shut up’ [on] the critical issues of [the nonmoving party’s] asserted causes of action.” *McDonough v. Memphis Radiological Prof’l Corp.*, 04-2697STA-TMP, 2009 WL 2179538, at *8 (W.D. Tenn. July 22, 2009) (cits. omitted), *aff’d sub nom.*, 440 F. App’x 487 (6th Cir. 2011). Ultimately, summary judgment must be entered “against a party who fails to make a showing sufficient to establish the existence of an element essential to that party’s case, and on which that party will bear the burden of proof at trial.” *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986).

B. To prevail on his FCA claim, Relator must prove the remuneration, inducement, and intent elements of the alleged AKS violations underlying that claim

Relator alleges that Mobilex violated the FCA. Am. Compl. at ¶¶ 108-113.²⁴ The FCA

²⁴ In Counts 3 through 9 of the Amended Complaint, Relator alleges that Mobilex also violated the Illinois, Massachusetts, Virginia, New York, Texas, Michigan, and Georgia state FCAs, respectively. With the exception of Michigan, these states’ FCAs have been construed to conform to the federal FCA. *Goldberg v. Rush Univ. Med. Ctr.*, 929 F. Supp. 2d 807, 816 (N.D. Ill. 2013); *U.S. ex rel. Ciaschini v. Ahold USA Inc.*, 282 F.R.D. 27, 37 (D. Mass. 2012); *U.S. ex rel. Bartz v. Ortho-McNeil Pharm., Inc.*, 856 F. Supp. 2d 253, 259 (D. Mass. 2012); *U.S. v. Universal Health Servs., Inc.*, 1:07CV00054, 2010 WL 4323082, *2 (W.D. Va. Oct. 31, 2010); *Cade v. Progressive Cmty. Healthcare, Inc.*, 1:09-CV-3522-WSD, 2011 WL 2837648, at *3 (N.D. Ga. July 14, 2011); *U.S. ex rel. Foster v. Bristol-Myers Squibb Co.*, 587 F. Supp. 2d 805, 808 n.2 (E.D. Tex. 2008). Mobilex’s arguments concerning the

creates civil liability for any person who “knowingly presents, or causes to be presented” to the Government “a false or fraudulent claim for payment or approval.” 31 U.S.C. § 3729(a)(1). “To establish a prima facie FCA violation under this section, [Relator] must prove that: (1) [Mobilex] presented or caused to be presented to an agent of the United States a claim for payment; (2) the claim was false or fraudulent; and (3) [Mobilex] knew the claim was false or fraudulent.” *U.S. ex rel. David Antoon v. Cleveland Clinic Foundation*, No. 3:12-cv-027, 2013 WL 5657597, at *7 (S.D. Ohio Oct. 16, 2013) (cit. omitted).

The FCA likewise creates civil liability for any person who “knowingly makes, uses or causes to be made or used a false record or statement to get a false or fraudulent claim paid or approved by the Government.” 31 U.S.C. § 3729(a)(2). “To establish a prima facie FCA violation under this section [Relator] must prove: (1) [Mobilex] made, used or caused to be made or used, a record or statement to get a claim against the United States paid or approved: (2) the record or statement and the claim were false or fraudulent; (3) [Mobilex] knew that the record or statement and the claim were false or fraudulent; and (4) the United States suffered damages as a result.” *Antoon*, 2013 WL 5657597, at *7 (cit. omitted).

Here, Relator alleges that Mobilex’s claims were false or fraudulent because Mobilex certified that it complied with the AKS, yet its services were “rendered to patients unlawfully referred to Mobilex by nursing homes to whom Mobilex provided kickbacks and/or illegal remuneration in violation of the [AKS].” Am. Compl. at ¶ 109. Relator’s prima facie FCA case therefore requires proof of the alleged AKS violations underlying his claims. To prove those AKS violations, Relator must show remuneration, inducement, and intent. Although the FCA is a civil statute, Relator seeks to show a violation of the AKS, which is a criminal statute.

federal FCA and the AKS therefore apply with equal force to Counts 3 through 9 of the Amended Complaint, except for Count 8 which deals with Michigan’s Medicaid program. Count 8 fails because there is no evidence in this case that Mobilex submitted false claims for payment to the Medicaid program in Michigan.

Accordingly, Relator bears the burden to show that Mobilex violated the FCA by preponderance of the evidence, but that Mobilex violated the specific requirements of the AKS beyond a reasonable doubt.

1. Relator must first prove remuneration and inducement and, if successful, still bears the burden of proving intent through testimony and contemporaneous documents

The AKS is a specific intent statute that makes it a crime to knowingly and willfully offer or pay any “remuneration” to induce referrals of Medicare business. 42 U.S.C. § 1320a–7b(b). “Remuneration” is defined broadly to include the transfer of anything of value, directly or indirectly, overtly or covertly, in cash or in kind. *Klaczak v. Consol. Med. Transp.*, 458 F. Supp. 2d 622, 626 (N.D. Ill. 2006). If Relator fails to make a preliminary showing of remuneration and inducement, then he cannot survive a motion for summary judgment. In that case, the Court does not even have to reach the issues of knowing and willful intent, or specific intent. *Id.*

In *Klaczak*, for example, the relator alleged that the hospitals enabled a swapping scheme by accepting below-FMV rates from an ambulance company on Medicare Part A transports in exchange for providing that company with exclusive or preferred access to Medicare Part B transports. *Id.* at 633. The relator’s failure to raise a jury question on remuneration by presenting a competitive market analysis showing below-FMV pricing led the U.S. District Court for the Northern District to grant summary judgment. *Id.* at 626. Even if the relator had presented such a competitive market analysis, the Northern District would still have granted summary judgment, because he did not produce “a comment, email, memo, or other indication by any relevant agent” to support the alleged scheme. *Id.* at 680.

The U.S. District Court for the Northern District of Mississippi applied the *Klaczak* framework in *U.S. ex rel. Jamison v. McKesson Corp.*, 900 F. Supp. 2d 683, 703 (N.D. Miss. 2012). The Government intervened in *Jamison* and tried the case to the district judge, arguing

that the defendant MediNet engaged in a swapping scheme to induce Medicare Part B referrals by offering remuneration to nursing homes in the form of billing services priced at (1) below FMV, (2) below cost, or (3) at an unlawful discount. *Id.* The Government's failure to prove one of those forms of remuneration and inducement, standing alone, was enough to demand a verdict in MediNet's favor. *Id.* Even if the Government had proven remuneration and inducement, its failure to prove MediNet's business people's intent through their testimony and contemporaneous documents would have still demanded a defense verdict. *Id.*

Klaczak and *McKesson* apply here. Mobilex has produced indisputable evidence that (1) there was no remuneration or inducement at any specific SNFs because Mobilex priced its Part A business at FMV and above cost, and (2) Mobilex's personnel lacked knowing and willful intent. Relator's failure to adduce evidence of below-FMV or below-cost pricing at a specific SNF, entitles Mobilex to summary judgment on claims relating to that specific SNF. Even if Relator comes forward with evidence of below-FMV or below-cost pricing at a specific SNF, *then he must still* point to Mobilex witness testimony and contemporaneous documents (e.g., emails, internal memoranda) raising a triable fact issue regarding Mobilex's alleged knowing and willful intent for that specific SNF in order to present the claims regarding that specific SNF to the jury.

2. Relator must prove that Mobilex acted “knowingly and willfully” and with specific intent in order to satisfy the heightened intent requirement for an AKS violation

The requirement that Relator prove that Mobilex acted “knowingly and willfully” means that Relator must prove that Mobilex meant to violate the law. *See United States v. McClatchey*, 217 F.3d 823, 829 (10th Cir. 2000). That is, Relator must show that Mobilex acted “intentionally and purposely and with the intent to do something the law forbids, that is, *with the bad purpose to disobey or to disregard the law.*” *Bryan v. United States*, 524 U.S. 184, 190 (1998) (emphasis added). For Medicare Part B claims submitted before March 23, 2010, Relator

must also show that Mobilex acted with the specific intent to induce referrals.²⁵ *McClatchey*, 217 F.3d, at 829. Inducement means more than hoping, or believing referrals may ensue; a party must act with the intent to exercise influence over the judgment of another with the intended result of causing the referral of Medicare business. *Hanlester Network v. Shalala*, 51 F.3d 1390, 1398 (9th Cir. 1995); *see also Polk County v. Peters*, 800 F. Supp. 1451, 1455 (E.D. Tex. 1992). Relator must put forward specific evidence that Mobilex had the specific intent of inducing referrals, and not just that it charged discounted prices and received Part B business.²⁶

3. Relator must prove all elements of the alleged AKS violations—remuneration, inducement, and intent—beyond a reasonable doubt

In addition, the AKS is a criminal statute. Thus, a relator attempting to establish a FCA case based on underlying AKS violations must first prove all essential elements of the AKS violation *beyond a reasonable doubt*. *Jamison*, 900 F. Supp. 2d at 698 (noting that the “proper course” in FCA cases based on underlying AKS violations is to use the criminal “beyond a reasonable doubt” standard). That is, Relator must prove each element of the AKS violation underlying his FCA claim beyond a reasonable doubt. Proving the AKS violation establishes that the claims for payment submitted to the government were false or fraudulent. Relator must prove each of the remaining elements of his FCA claim by a preponderance of the evidence in order to prevail on the merits.

²⁵ Effective March 23, 2010, Congress reduced the intent level required for an AKS violation. The statute now reads: “With respect to violations of [the AKS], a person need not have actual knowledge of this section or specific intent to commit a violation of this section.” 42 U.S.C. § 1320a-7b(h). This amendment is not retroactive. *Graham County Soil & Water Conservation Dist. V. United States ex. Rel. Wilson*, 559 U.S. 280, 283 n.1 (2010).

²⁶ In *U.S. v. Neufeld*, 908 F. Supp. 491, 497 (S. D. Ohio 1995), Judge Smith declined to adopt the *Hanlester* definition of willful intent in a constitutional challenge to the AKS. While Judge Smith held that the “formulation of ‘willful’ which takes into account the purpose to commit a wrongful act” was sufficient to eliminate the constitutional challenge, he declined to specifically define the scienter requirement. *Id.* Since then, Judge Frost has analyzed the scienter requirement under both *Hanlester* and the lesser standard referenced in *Neufeld*, signaling that the meaning of willful intent remains unsettled in this judicial district. *McDonnell v. Cardiothoracic & Vascular Surgery Assocs., Inc.*, No. C2-03-79, 2004 WL 3733402, at *8-9 (S.D. Ohio July 28, 2004). Mobilex submits that *Hanlester* sets forth the correct definition of willful intent for Medicare Part B claims before March 23, 2010. Otherwise, Congress would not have had a reason amend the statute to lower the scienter requirement.

C. McDonough cannot show a genuine issue of material fact on the remuneration and inducement elements required for an AKS violation

Relator alleges that Mobilex has provided remuneration to its SNF customers by offering rates on Part A business that are (1) below FMV, (2) below cost, or (3) below the MFS, by foregoing its collection of accounts receivable, and by keeping shoddy records in order to prevent Apex Radiology from billing unspecified SNFs.

The undisputed material facts demonstrate that Relator lacks evidence to support his claims. Mobilex, however, has shown that it priced at FMV and above its cost. *Yarin Rpt.* at 13-14; *see e.g. McCarthy Rpt.* at 15. Relator himself concedes that prices set below the MFS are lawful, despite his statement in his Amended Complaint. *R. Dep.* at 178-180. Further, Relator's remaining theories of remuneration have no factual basis. Because Relator cannot adduce evidence of below-FMV or below-cost pricing sufficient to raise a jury question, and because he has admitted that pricing below the MFS is not unlawful, there is no genuine issue of fact regarding Relator's inability to establish remuneration and inducement. Mobilex is thus entitled to summary judgment.

1. Relator cannot adduce evidence showing that Mobilex's rates were below FMV

Federal courts use FMV pricing as a gauge for the remuneration element of an AKS offense. *Jamison*, 900 F.Supp.2d at 699. FMV is defined as the value in an arm's-length transaction that is consistent with the general market value.²⁷ *IRS Revenue Ruling 59-60; see also BLACK'S LAW DICT.* 1691 (9th ed. 2009). Rates do not have to be the highest in the market

²⁷ Ms. McNamara, in her report, inappropriately applies a definition of FMV that is not relevant to a discussion under the AKS. Instead she attempts to lift an inapplicable FMV definition from the so-called "Stark" statute. *McNamara Rpt.* at 7. The Stark law is a strict liability statute that has a very narrow focus: it applies only to financial arrangements between a referring physician and certain healthcare providers. *Kevin McAnaney Rebuttal Report ("McAnaney Reb. Rpt.")* at 1 (attached hereto as Exh. 22). The Stark law is inapplicable to this case. No court has ever accepted her misreading of the Stark law when analyzing the AKS, and no principle of statutory construction would ever justify porting one definition from an unrelated civil statute into a criminal specific intent statute.

to be considered within FMV. *Jamison*, 900 F. Supp. 2d at 700. A bid that is not the lowest and not unreasonable when viewed alongside other bids is not below FMV. *Id.*

Mobilex has demonstrated through documents and testimony that the SNF market for mobile x-rays services is highly competitive and that Mobilex's negotiated rates reflect that competition. Section II.B.2. Rates negotiated in a highly competitive market are, by definition, FMV. McCarthy Rpt. at 9. Mobilex has also shown that its contract rates with prisons—which have neither Part A patients nor Part B business to refer—are generally consistent with its average rates for the 348 SNFs targeted by Relator. Section II.B.6. It is undisputed that when evaluating its SNF rates, Mobilex considers its prison rates as reference points for gauging FMV. Glynn I Dep. at 144-145. Relator has adduced no evidence to the contrary.

In order to establish that Mobilex provided remuneration by pricing below FMV at a specific SNF, Relator would have to come forth with a competitive market analysis. That is, he would have to first present admissible evidence of what the FMV for portable x-ray services was in the specific SNF's market, based upon the prices charged by competitors of Mobilex providing portable x-ray services. Then he would have to show that Mobilex's Part A pricing at the specific SNF fell below that range. *Klaczak*, 458 F. Supp. 2d at 626, 678-680. Relator has not even tried to do a competitive market analysis in this case.

Instead, Relator has produced Kathy McNamara as his putative expert. McNamara is an accountant, but seeks to interpret HHS-OIG's non-binding sub-regulatory guidance and assume it is the law.²⁸ She believes, contrary to case law, that a competitive market analysis is

²⁸ From the outset of this case, Relator has maintained that HHS-OIG's sub-regulatory guidance (*e.g.*, advisory opinions) has the force of law. His putative expert parrots this position, although she is not a lawyer. They are both wrong. Such guidance does not establish a legal or regulatory standard for measuring AKS compliance. *Christensen v. Harris County*, 529 U.S. 576, 587 (2000) (explaining that an agency's statutory interpretations in opinion letters, policy statements, manuals, and enforcement guidelines, "all of which lack the force of law," do not receive judicial deference). Indeed, HHS-OIG's sub-regulatory guidance is not even given deference within HHS, its parent agency. Kevin McAnaney Report ("McAnaney Rpt.") at 11 (attached hereto as Exh. 23). (citing

categorically improper because the mobile x-ray industry is, or could be, tainted with illegal swapping practices. McNamara Rpt. at 14. At the same time, McNamara admits that she did not perform an analysis or conduct any research to support her conclusion. McNamara Dep. at 80:10-21. As Mobilex will explain in its forthcoming Motion to Exclude McNamara's testimony, which is forthcoming, McNamara is either drawing an impermissible and incorrect legal conclusion from that guidance, or making an inferential leap from that guidance without factual support. Either way, neither she nor Relator has identified a colorable factual basis for finding industry-wide wrongdoing, much less conducted a competitive market analysis.

In lieu of a competitive market analysis, McNamara opines that Mobilex's Part A rates are FMV only if they equal Mobilex's total costs (including all corporate overhead), plus a profit margin of 2% to 5%. McNamara Rpt. at 11. There is no AKS case law adopting the "cost-plus" definition of FMV that Relator has concocted for his putative expert to articulate. Instead of relying on the definitions of FMV in the AKS itself, Relator seeks to concoct his own FMV definition that is not supported by the AKS. Regardless, Mobilex is entitled to summary judgment, because McNamara's unreliable opinions are inadmissible for the reasons which Mobilex will explain in its forthcoming Motion to Exclude.

2. Relator cannot adduce evidence showing that Mobilex's rates were below cost

Mobilex's incremental cost approach is an appropriate method for measuring costs under the AKS. Indeed, it was accepted by the Northern District of Mississippi last year in *Jamison*,

HHS Dept. Appeals Board Decision No. 1275, Medicare & Medicaid Guide (CCH) 1992-1 MED-GUIDE-TB ¶ 39,566, § V.C.5 (Sept. 18, 1991). HHS has gone so far as to expressly limit the use of HHS-OIG advisory opinions in court by including standard limiting language in its recent advisory opinions. *See e.g.* AO 13-14 (stating: "This advisory opinion may not be introduced into evidence by a person or entity other than [county name redacted] to prove that the person or entity did not violate the provisions of sections 1128, 1128A, or 1128B of the Act or any other law."). Relator and McNamara's position that HHS-OIG's sub-regulatory guidance has the force of law is not only contrary to binding Supreme Court precedent and HHS's understanding, but is also contrary to the consensus position of the national health care regulatory community during the relevant time period. McAnaney Rpt. at 11; Dep. of Kevin McAnaney ("McAnaney Dep.") at 114 (all excerpts attached hereto as Exh. 24).

where the Government intervened, took the case to trial, and argued that MediNet engaged in a swapping scheme by pricing its services below its costs. 900 F. Supp. 2d at 689. The Government's theory was that MediNet negotiated its rates using cost analyses that improperly excluded fixed costs and overhead, *e.g.*, executive salaries and property costs, which would be incurred regardless of whether MediNet won the contract or not. 900 F. Supp. 2d at 700-01. Instead, MediNet's cost analyses included only those incremental costs (also referred to as average variable costs) that were expected to increase as a result of the new contract. *Id.* After a two-week bench trial in which the defense rested at the end of the Government's case, the U.S. District Court for the Northern District of Mississippi flatly rejected the position that the incremental cost approach is categorically unlawful or improper. *Id.* ("The Government sought to highlight the fact that an incremental cost analysis was not the proper way to analyze profitability of a contract; however, Plaintiff failed to present evidence that such analysis was either illegal under the AKS or improper under standard accounting principles."). Yet Relator here seeks to do exactly the same – he cannot show by any statute or case law that an incremental cost analysis is illegal or improper under the AKS, so he simply asserts it is so. This is not sufficient to allow this case to go to the jury.

It is undisputed that Mobilex's average Part A rate per encounter for the 348 SNFs targeted by Relator exceeds Mobilex's corporate-wide incremental costs per encounter. Yarin Rpt. at 13-14. Relator has not—and cannot—come forward with any evidence to raise a triable issue of fact concerning Mobilex's pricing of its Part A services above its incremental costs. Instead, Relator relies exclusively on Ms. McNamara for the position that the incremental cost method is categorically unlawful and improper under the federal health care laws and HHS-OIG sub-regulatory guidance, and total cost is the only lawful and appropriate measure. Relator's

argument is wrong as a matter of law under *Jamison*. Relator is unable to point to any language in the AKS or its implementing regulations making it unlawful to use the incremental cost method. Moreover, it is undisputed that using the incremental cost method is widely accepted as an appropriate accounting practice. *See* John Sullivan Report (“Sullivan Rpt.”) at 4, 9 (attached hereto as Exh. 25). McNamara’s putative “expert” opinion on “FMV” is a Trojan horse for an improper and incorrect legal opinion that is not only inadmissible, but also inconsistent with generally accepted and appropriate accounting practices. Once the Court removes the fig leaf of McNamara’s legal opinion from Relator’s case, the Court must grant summary judgment in Mobilex’s favor on Relator’s below-cost theory of remuneration.

3. Mobilex may lawfully price below the MFS, which is not a proxy for FMV

Pricing below the MFS is lawful. *Klaczak*, 458 F.Supp.2d at 679-80. The position that pricing below the MFS constitutes remuneration *per se* has no basis in the AKS. *Id.* This is because the MFS is not a proxy for FMV. *Id.* As the Northern District of Illinois recognized in *Klaczak*, the Medicare Fee Schedule price is just that: a price that one payor will pay for a service. *Id.* Relator’s allegation that Mobilex’s pricing below the MFS is remuneration *per se* is simply wrong as a matter of law. Indeed, Relator conceded this point at his deposition, when he testified that discounting off the MFS may be permissible depending on the situation. R. Dep. at pp. 178-180. Relator’s putative expert, Kathy McNamara, has provided similar testimony. *See generally* McNamara Dep. at 61:1-6. Because Relator now agrees with Mobilex that pricing below the MFS can be lawful, Mobilex is entitled to summary judgment on that theory of remuneration.

4. Mobilex has not written-off accounts receivable on Part A business with SNFs in order to induce referrals of Part B business

Relator has alleged in this case that Mobilex gave kickbacks to SNFs for Part B business by systematically failing to collect its accounts receivable. Am. Compl. at ¶¶ 92-98. There is no factual basis for that allegation: it is undisputed that for the 348 SNFs targeted by Relator, Mobilex collected more than █████ of the amounts which it billed to those SNFs. Yarin Rpt. at 13. Mobilex adjusted only █████ of the charges billed directly to those SNFs—a statistic which is “within, if not better than the industry norm.” *Id.* at 15. Those adjustments were not whimsical. Rather, Mobilex made adjustments when a salesperson found a typo, a payment posted to the incorrect invoice, an account closed with less than █████ balance, or a client filed for bankruptcy. Dep. of Patricia Falice (“Falice Dep.”) at 76:9, 76:19, 77:7, 203:6 (all excerpts attached hereto as Exh. 26). Relator has not and cannot come forward with evidence substantiating his conclusory allegations of systematic write-offs, allegations that lack factual evidentiary support and therefore cannot create a triable fact question. *Alexander*, 576 F.3d at 560 (“Conclusory statements unadorned with supporting facts are insufficient to establish a factual dispute that will defeat summary judgment.”). Mobilex is therefore entitled to summary judgment on his theory that Mobilex systematically wrote-off accounts receivable with SNFs to induce Medicare Part B referrals. Even if that theory had merit (which it does not), Relator has failed to identify any specific SNF that had its accounts receivable forgiven or written off.

5. Mobilex did not interfere with Apex Radiology’s billing by keeping poor records

Relator somehow attempts to stand in the shoes of one of Mobilex’s contracted radiology companies. He alleges that Mobilex prevented a radiologists’ practice (Apex Radiology) from billing its professional services to Medicare by failing to maintain the accurate records which Apex required in order to bill the SNFs. Such alleged poor record keeping supposedly shows

that Mobilex intended to confer remuneration on the SNFs through Apex. Am. Compl. at ¶¶ 99-103. Yet again, the incontrovertible evidence shows that Relator's conclusory allegation is without merit. The contract between Apex and Mobilex states that Apex receives payment only from Mobilex and not the Government, and requires Apex to work with Mobilex so that Mobilex can bill Medicare. Glynn Dec. at ¶ 15, Attach. 1. This evidence is insufficient to establish the indirect remuneration Relator alleges, and the lack of evidentiary support demands summary judgment in favor of Mobilex with respect to Relator's theory of indirect remuneration through Apex. Even if Relator's Apex theory had merit (which it does not), Relator has failed to identify a specific claim which Apex was unable to bill to a specific SNF as a result of Mobilex's supposedly poor recordkeeping.

6. Mobilex's pricing arrangements qualify for the discount statutory exception

Even if Relator could, *arguendo*, raise a genuine issue of material fact regarding remuneration and inducement, Mobilex is still entitled to summary judgment under the discount statutory exception under the AKS. That exception provides that the AKS does not apply to: (i) a discount or other reduction in price; (ii) given to a provider of services or other entity under a Federal health care program; (iii) if the discount is properly disclosed and reflected in the costs claimed or charges made by the provider or entity under the Federal health care program. 42 U.S.C. §1320a-7b(b)(3)(A). Mobilex's billing to SNFs is transparent and open. The rates charged for the services are set forth in the SNF contracts and in the monthly invoices provided to the SNFs. Glynn Dec. at ¶ 7. The SNFs then must reflect these charges in their filed cost reports with CMS. 42 CFR 413.20. Mobilex is entitled to assume that its contracted SNFs have submitted their cost reports correctly and have not violated any laws. *Cf. U.S. v. Tarwater*, 308 F.3d 494 (6th Cir. 2002) (affirming that defendant is presumed innocent until proven guilty).

Relator has not—and cannot—show that Mobilex failed to disclose these rates to a particular SNF, much less show that a SNF’s legally-required cost reporting failed to identify that the SNFs payments for Mobilex’s services. Accordingly, Mobilex is entitled to summary judgment on all of Relator’s claims under the discount statutory exception.

D. Relator cannot prove that Mobilex acted with the bad purpose to disregard or to disobey the law generally, much less the AKS in particular

There is no genuine issue of material fact that Mobilex intended to comply with the law (including the AKS) by negotiating profitable contracts with SNFs, and under which the Medicare Part A business would be profitable independent of any Medicare Part B business received by Mobilex through the SNF. The witness testimony establishing this fact is simply indisputable. Williams Dep. at 71; Glynn I Dep. at 60:2-7, 125:20-22, 145:20-23; Reichert Dep. at 144-145; Hooper Dep. at 16-17. This was true regardless of whether Mobilex was negotiating a contract with an individual SNF, or a chain encompassing numerous SNFs. Reichert Dep. at 148. The undisputed evidence establishes that Mobilex has been profitable at the consolidated corporate level every year since at least 2004. *See* Cuomo Dec. ¶¶ 10-18.

Relator has argued that Mobilex should have negotiated contracts using its actual total costs at the SNF or individual exam level as a baseline. Mobilex, however, does not use an actual, SNF-specific measure of cost when negotiating, because it is impracticable to do so due to service variability. Section II.B.4, above. Indeed, the evidence shows unequivocally that *no one in the mobile x-ray industry* negotiates using actual costs at the SNF or individual exam level for that very reason. Cuomo Dec. at ¶ 20. The fact that Mobilex foregoes an impracticable business analysis is not evidence of bad purpose, but rather sound business judgment. This is especially true when the very business practice which Mobilex undertakes—trying to negotiate contracts which are profitable and, at a minimum, cover the anticipated cost to provide the

service—was accepted as lawful in *Jamison*. Relator cannot point to any law that requires Mobilex to do the impracticable in order to comply with the AKS.

The evidence is also undisputed that Mobilex implemented and ultimately enhanced its annual rate review with the specific intent to comply with the AKS. Section II.B.5, above. Mobilex's systematic assessment and increasing of its rates shows unequivocally that Mobilex conducted its rate reviews in good faith and effectively. Even Relator's expert admits that Mobilex's rate review program is effective. Section II.B.5 above. Relator cannot point to any Mobilex witness testimony, emails, internal memoranda, correspondence with SNFs, or the like which raises a triable fact issue concerning Mobilex's intent to comply with the AKS and the law generally through its rate review program and its sensible contracting practices.

Instead, Relator relies upon his flawed legal construction of the HHS-OIG guidance—and Ms. McNamara's parroting of the same—to try to prove the requisite knowing and intent through a supposed pattern or practice of below-FMV or below-cost pricing. Relator summarily argues that transferring anything of value at less than fair market value infers that remuneration is being offered to induce referrals. Setting aside the fact that HHS-OIG's sub-regulatory guidance is nonbinding and lacks the force of law, Relator's legal construction of the HHS-OIG guidance is wrong. HHS-OIG looks first to see if the provider's Part A discounts are "'suspect' in the sense that they may merit further investigation depending on the facts and circumstances presented." McAnaney Rpt. at 7 (citing April 20, 2000 letter posted to OIG website). Discounts that are "particularly suspect" include:

- Discounted prices that are below the supplier's average cost, including both fixed and variable costs;
- Discounts that are offered selectively to customers in a position to generate Medicare Part B or other federal health care business;

- Discounts on Medicare Part A business coupled with supplier exclusivity; and
- Discounts on items or services to capitated or all-inclusive payment patients in conjunction with an explicit or implicit agreement to refer other federal health care program business.

Id. at 6. HHS-OIG's identification of a given practice as "suspect" does not mean it is necessarily illegal or unlawful. *Id.* at 7. The "suspect" nature of a practice simply triggers a second step for HHS-OIG: further investigation. Only after further investigation can HHS-OIG determine whether the provider has the requisite intent for an AKS violation. That determination cannot be made based only on a conclusion that the pricing at the specific SNF is below FMV or cost.

Even Relator's putative expert agrees. In her deposition Ms. McNamara admitted that her report was incorrect, and that it is not illegal to offer discounted services below total costs. McNamara Rpt. at 33. She conceded that there is no OIG guidance which states that it is illegal to offer SNFs discounted services below total costs. McNamara Dep. at 17:18-25. She explained that it would only be a "suspect" arrangement. *Id.*

Relator's theory of intentional noncompliance is not supported by any specific evidence—emails, memoranda, financial analyses, witness testimony, or the like—of the negotiations or rates for any individual SNFs. Relator's putative expert even conceded that she has seen no such information. *See generally* McNamara Dep. Moreover, Relator is trying to go to a jury under the theory that Mobilex induced a SNF to make Part B referrals through contracts that Mobilex did not even negotiate. A quick perusal of those 11 SNFs identified in Paragraph 78 of the Amended Complaint shows that 2 of the 11 SNF contracts were acquired when Mobilex purchased a competitor in the Ohio market. R. Dep. at 197:12-198:6. Indeed, a substantial number of those facilities named in McNamara's report were not negotiated by

Mobilex. Relator offers nothing to overcome the glaring deficiency in his theory that Mobilex engaged in intentional wrongdoing, when it did nothing more than inherit a pre-existing contract. Relator's lack of evidence to support his allegations of intentional noncompliance make summary judgment in favor of Mobilex appropriate.

E. Alternatively, the Court should grant partial summary judgment and limit this case to Relator's claims on the three SNFs remaining from the Amended Complaint

Since the beginning of this litigation, it has been abundantly clear that Relator is focused upon the 11 SNFs originally identified in Paragraph 78 of the Amended Complaint. Relator originally agreed to limit discovery to those SNFs, and Mobilex produced large amounts of documents related to them. Mobilex, for instance, produced hard copy contract files for all of the 11 SNFs, plus *all* charge and payment data for *all* facilities which it served during the relevant time period. Of the original 11 SNFs, Relator now concedes that the rates for eight were *above* Mobilex's costs and FMV, *even under Relator's cost and FMV theories*. Section II.C, above. If the Relator's unsubstantiated factual allegations and flawed damages model are determined to be sufficient to survive summary judgment, the Court should nevertheless narrow the case to the only three SNFs for which Relator has made such allegations and also produced a damages model.

Mobilex should not now be forced to litigate claims regarding the other 6,000-plus facilities that it serves when Relator has been unable to present evidence regarding the original 11 SNFs in his Amended Complaint. If the Court declines to grant summary judgment, or partial summary judgment narrowing the case to the remaining three of the 11 SNFs, then Relator should not be allowed to proceed to trial on any SNF that came to Mobilex through an acquisition of a competitor. As set forth above, it defies logic that Mobilex could have engaged in a swapping scheme with a SNF when Mobilex did not even negotiate the contract (or even

increased the rate after the acquisition). Failure to grant at least partial summary judgment here has the effect of transforming AKS violations from criminal offenses—which requires knowing and willful intent—into civil ones which can be proven using only unreliable statistical proofs. Such a result is contrary to existing law and would be unjust under the circumstances reflected by the evidence.

IV. CONCLUSION

Because all of Relator's claims against Mobilex fail as a matter of law and there is no genuine issue of material fact summary judgment should be granted in favor of Mobilex. In the alternative, Mobilex requests that this case be limited to the three SNFs initially identified in the Amended Complaint and that are included in Relator's damages model.

Mobilex requests an oral argument as it will likely aid this Court in better understanding the arguments presented in this Motion.

Respectfully submitted,

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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
EASTERN DIVISION

UNITED STATES OF AMERICA, <i>ex rel.</i>)	
KEVIN P. MCDONOUGH, <i>et al.</i> ,)	
)	
Relator,)	
)	
v.)	CIVIL ACTION NO.
)	2:08-CV-0114
)	
SYMPHONY DIAGNOSTIC SERVICES, INC.)	
and SYMPHONY DIAGNOSTIC SERVICES)	JUDGE MARBLEY
NO. 1, INC., d/b/a MOBILEX U.S.A)	
)	MAGISTRATE JUDGE ABEL
)	
Defendants.)	
_____)	

CERTIFICATE OF SERVICE

This is to certify that I have this day served upon all counsel of record a copy of the within and foregoing "Motion and Supporting Memorandum of Law of Defendant Motion for Summary Judgment" via Federal Express, as follows:

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This 12th day of November, 2013.

/s/ Robert Cohen

Robert Cohen